

REMARKS/ARGUMENTS

The claims pending in the application following entry of the foregoing amendments will be Claims 29-57. Claims 1-28 have been cancelled.

The specification has been amended to reflect the status of the parent application (i.e., now U.S. Patent No. 6,319,464). Page 6 of the application has also been amended to correct the chemical names of two of the preferred amino alcohols utilized in the present invention. The amino alcohols in question (i.e., AMP and DMAMP) are commercially available and are commonly identified by both the acronyms utilized in the present specification and the corresponding chemical names, as demonstrated by a product guide published by Angus Chemical Company in 1995 (copy attached). Thus, correction of the chemical names for AMP and DMAMP in the specification does not introduce new matter into the present application.

Page 6 of the present application has also been amended to change the term "AMP-95" to -- AMP (95%) --. This revision has been made because "AMP-95" is a registered Trademark of the Angus Chemical Company. Corresponding revisions have been made in Examples 2-7 of the present application.

The paragraph bridging pages 8 and 9 of the present application has been amended to correct a misspelling of xylitol, and to include a sentence regarding the specification of U.S. Patent No. 5,505,953 (Chowhan), which is incorporated by reference in the present application. The sentence added regarding the disclosure of the '953 patent provides antecedent support in the specification for recitation of propylene glycol as a polyol in the claims of the present application (i.e., Claims 31, 34, 40, 43, 52 and 55).

Page 9 of the present application has been amended to identify the U.S. patent corresponding to Serial No. 08/381,889.

Page 11 of the present application has been amended to correct the names of the amino alcohols AMP and DMAMP. The basis for these amendments has already been discussed above.

Claims 13-28 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite. This rejection is now moot in view of the cancellation of Claims 13-28. The objections set forth in the last three paragraphs on page 2 of the outstanding Official Action

have been noted during the course of drafting of new Claims 29-57. It is believed that the new claims are in compliance 35 USC §112, second paragraph. In particular, the new claims recite appropriate units (i.e., grams/mole) relative to the molecular weight range recited in Claim 29 and other claims for the amino alcohols utilized in the present invention, and all of the dependent claims clearly further limit the respective claims from which they depend.

Newly submitted Claims 29-46 are composition claims which generally correspond to prior Claims 13-21. However, the new set of claims (i.e., Claims 29-46) includes additional dependent claims directed to preferred embodiments of the present invention. For example, Claims 31-34, 38 and 40-43 are directed to preferred polyols utilized in the borate/polyol complexes described in the present application, and Claim 36 is directed to preferred amino alcohols described in the application. Claim 44 is directed to an embodiment of the present invention wherein the ophthalmic composition does not contain a conventional antimicrobial preservative.

As indicated in the last paragraph on page 5 of the application, the present invention is based in part on a finding that the claimed amino alcohol/borate compositions function to preserve ophthalmic compositions against microbial contamination, and in some cases totally eliminate the need for a conventional anti-microbial preservative agent. This is a particularly desirable aspect or feature of the present invention, since the use of conventional anti-microbial preservatives (e.g., benzalkonium chloride) have been associated with adverse effects on the cornea and other ocular tissues.

Claims 45 and 46 are directed to ophthalmic compositions that are adapted for use as artificial tears and ocular lubricants, respectively. Support for the limitations recited in these claims is provided in the last full paragraph on page 7 of the present application. The phrase "adapted for use" in Claims 45 and 46 further limits the ophthalmic compositions encompassed by Claims 29-44, because, as person skilled in the art will readily appreciate, artificial tears and ocular lubricants have certain required features, such as electrolytes to simulate the chemical composition of human tears and/or demulcents to provide a hydrating or lubricating effect.

The preferred concentration ranges for the borate and polyol components of the compositions of the present invention recited in Claim 35 are supported by the written description of the invention provided in lines 4-7 on page 9 of the present application.

Newly submitted Claims 47-49 are directed to aqueous solutions for disinfecting contact lenses. These claims have been submitted in place of prior Claims 22-26. Claims 48 and 49 are directed to disinfecting solutions containing preferred amino alcohols.

Claims 49-57 are directed to preferred multi-dose ophthalmic compositions of the present invention, wherein the compositions are adapted for use as artificial tears or ocular lubricants and do not contain a conventional anti-microbial preservative.

Claims 1-28 were rejected under the judicially created doctrine of obviousness-type double patenting, based on Claims 5-12 of related U.S. Patent No. 6,319,464. This rejection is now moot in view of the cancellation of Claims 13-28. (Claims 1-12 were previously cancelled.) However, in the event the Examiner asserts the above-cited doctrine relative to the newly submitted claims (i.e., Claims 29-53), Applicants respectfully request that the Examiner enter the Terminal Disclaimer that accompanies this amendment.

In view of the foregoing amendments and remarks, favorable reconsideration in the form of a Notice of Allowance is respectively requested.

Respectfully submitted,
ALCON RESEARCH, LTD.

1/27/05
Date

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Attachment: Product Guide Published by Angus Chemical Co.

BEST AVAILABLE COPY

Guide to
Our
Products

ANGUS
CHEMICAL COMPANY

BEST AVAILABLE COPY IN O A L C O H O L S

AMP Regular^{*} and AMP-95^{*}

Powerful multifunctional amino alcohol that can be used as a co-dispersant, solubilizer, co-emulsifier, stabilizer, neutralizer, buffer and component of acid-salt catalyst in a wide range of markets. Raw material (2-amino-2-methyl-1-propanol) for synthesis.

AEPD^{*} Regular/AEPD^{*}-85

Polyfunctional amino alcohol used as dispersing aid, chemical intermediate, co-emulsifier, formaldehyde scavenger and component of acid-salt catalyst. Raw material (2-amino-2-ethyl-1,3-propanediol) for synthesis.

TRIS AMINO^{*}

Tris(hydroxymethyl)aminomethane Polyfunctional raw material for resin synthesis, preparation of oxazolines and oxazolidines; effective amine buffer in cosmetic or diagnostic aid formulations. Available as concentrate or crystals.

DMAMP-80^{*}

Potent co-emulsifying agent for waxes; amine solubilizer for resins in water-based coatings; urethane catalyst; titanate solubilizer. Raw material (2-dimethylamino-2-methyl-1-propanol) for synthesis.

Amino Alcohols (Nitro Alcohol derivatives)

AMP Regular^{*}
CH3C(CH3)(NH2)CH2OH
2-amino-2-methyl-1-propanol

AMP-95^{*}

AEPD^{*}
2-amino-2-ethyl-1,3-propanediol
HOCH2C(C2H5)(NH2)CH2OH

AEPD^{*}-85

TRIS AMINO^{*}
tris(hydroxymethyl)aminomethane
(HOCH2)3CNH2
Technical Grade

TRIS AMINO^{*}
Ultra Pure

TRIS AMINO^{*}
Concentrate

TRIS HYDROCHLORIDE,
ULTRA PURE
tris(hydroxymethyl)aminomethane
hydrochloride

Seritol
2-amino-1,3-propanediol
HOCH2CH(NH2)CH2OH

DMAMP-80^{*}
2-dimethylamino-2-methyl-1-propanol
(CH3)2NC(CH3)2CH2OH

AB^{*}
2-amino-1-butanol
CH3CH2CH(NH2)CH2OH

AMPD^{*}
2-amino-2-methyl-1,3-propanediol
HOCH2C(CH3)(NH2)CH2OH

Neutral equivalent

Water % by wt. (max.)

Melting point °C

Solubility in water at 20°C, g/100mL

Uses

| | | | | | |
|--|------------|-----|---------|-------|--|
| AMP Regular [*] <chem>CH3C(CH3)(NH2)CH2OH</chem> 2-amino-2-methyl-1-propanol | 88.5-91 | 0.8 | 30 | misc. | <ul style="list-style-type: none"> Multifunctional additive for latex paint Pigment co-dispersant Solubilizer for hair fixative, coating and other resins Emulsifying amine (with fatty acids) Buffer for alkaline phosphatase reactions Catalyst (as acid salt) Cosmetic ingredient and raw material |
| | 93-97 | 5.8 | -2 | misc. | |
| AEPD [*] 2-amino-2-ethyl-1,3-propanediol <chem>HOCH2C(C2H5)(NH2)CH2OH</chem> | 124 max | 3.8 | 38 | misc. | <ul style="list-style-type: none"> Chemical intermediate Formaldehyde scavenger Acid-salt catalyst for permanent-press resins Emulsifying amine (with fatty acids) |
| | - | 15 | <-24 | misc. | |
| TRIS AMINO [*] tris(hydroxymethyl)aminomethane <chem>(HOCH2)3CNH2</chem> Technical Grade | 121-122 | 0.5 | 160 min | 80 | <ul style="list-style-type: none"> Chemical intermediate Resin-synthesis intermediate Neutralizing amine in cosmetics Buffer for enzyme and diagnostic testing Pharmaceutical buffer and solubilizer Formaldehyde scavenger |
| | - | 0.2 | 170-172 | 80 | |
| TRIS AMINO [*] Concentrate | - | 60 | - | misc. | <ul style="list-style-type: none"> Biological/biochemical buffer |
| | - | - | 152 | misc. | |
| Seritol 2-amino-1,3-propanediol <chem>HOCH2CH(NH2)CH2OH</chem> | - | 0.5 | 52-56 | - | <ul style="list-style-type: none"> Pharmaceutical intermediate Synthesis intermediate |
| | - | - | - | - | |
| DMAMP-80 [*] 2-dimethylamino-2-methyl-1-propanol <chem>(CH3)2NC(CH3)2CH2OH</chem> | 148 | 20 | -20 | misc. | <ul style="list-style-type: none"> Resin neutralizer/solubilizer Emulsifying amine (with fatty acids) Synthesis intermediate |
| | - | 0.5 | -2 | misc. | |
| AB [*] 2-amino-1-butanol <chem>CH3CH2CH(NH2)CH2OH</chem> | - | 0.5 | -2 | misc. | <ul style="list-style-type: none"> Pharmaceutical intermediate Chemical intermediate Neutralizing amine |
| | - | - | - | - | |
| AMPD [*] 2-amino-2-methyl-1,3-propanediol <chem>HOCH2C(CH3)(NH2)CH2OH</chem> | 103-107 | 0.5 | 100 min | 250 | <ul style="list-style-type: none"> Reagent chemical in medical diagnostic tests Solubilizer or emulsifier system component in premium personal care products Buffer for aqueous systems |
| | - | - | - | - | |

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